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The official link for this solicitation is: http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-14-010.html

Agency:
Department of Health and Human Services

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1

Description:

For more than a decade, cognitive training has been explored as an intervention in a variety of neuropsychiatric disorders such as Attention Deficit Hyperactivity Disorder, anxiety, autism spectrum disorders (ASD) and schizophrenia, targeting specific impairments in neural system functioning at different ages across the lifespan. These interventions have used various approaches, including training of perceptual processes, drill-and-practice techniques focused on learning via repetition and feedback, problem solving and concept formation practice, and methods designed to enhance compensatory cognitive processes.

Several of these interventions have been developed as computer-based programs with demonstrated efficacy at improving neurobehavioral function, yet improvements in real world function have been less clear. Overall there has been a significant lag in the full development and validation of computer-based cognitive training for neuropsychiatric treatment, in part due to the cross disciplinary expertise needed in developing engaging, immersive computer programs that specifically target neural systems implicated as treatment targets for neuropsychiatric deficits.

The entertainment software industry has a demonstrated capability in rapidly developing engaging, scalable, and commercially successful products. However, this industry has focused mostly on game development and not health interventions. New interest in developing computer game-based approaches to address health has emerged in recent years, and may offer fresh opportunities to apply highly engaging methods to the improvement of health functioning and outcomes.

Given the promise of computer-based cognitive training and the experience of the entertainment software industry at rapidly developing engaging, scalable, and commercially successful products, there is an opportunity for cross-disciplinary collaboration to further develop promising computer-based interventions. The NIMH has developed this FOA to encourage partnerships between small businesses in the entertainment software sector and clinical neuropsychiatry researchers with demonstrated track records in neuroplasticity and cognitive training research, to further develop these interventions. Ultimately, if successful, these interventions could be disseminated widely and quickly through commercialization.

This NIMH SBIR FOA is informed by two recent meetings: 1) the inaugural meeting of the Entertainment Software and Cognitive Neurotherapeutics Society (ESCoNS) in September 2011, where representatives from the entertainment software community, neuroscientists, and the NIH came together to establish potential partnerships for the development of cognitive neurotherapeutics; and 2) the NIMH-sponsored meeting “Cognitive Training in Mental Disorders: Advancing the Science” in April 2012, which focused on next steps in the further development, validation and implementation of cognitive training interventions, including a focus on novel and multi-component interventions and new therapeutic targets.

It is expected that products developed from this FOA will be drawn from interventions with demonstrated efficacy and a strong scientific rationale for the treatment target and intervention modality. Highest priority will be given to interventions that target functional domains implicated in neuropsychiatric disorders (e.g., attention, working memory, social cognition, affect regulation, attention bias), and the neurocircuitry underlying the targeted domain. A strong scientific justification for the choice of neuropsychiatric disorder and age of research participants is also required.

It is expected that the proposed partnerships would include groups with demonstrated track records in the areas of neural plasticity and cognitive training research, and the successful development and commercialization of entertainment software programs. Phase I of this pilot program would serve as a vehicle for the primary research and development, and will include initial feasibility testing. It is expected that at the completion of Phase I the applicant will have developed a working prototype. In Phase II, it is expected the applicant will formally evaluate the product utilizing an appropriately powered efficacy study that includes validated cognitive outcome measures and validated measures of functional outcome. The applicant should also ensure the final product is in compliance with FDA regulatory guidelines, by initiating the pre-IDE process: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#pre_ide.

In addition, the technology platform used in the application should be flexible enough to allow future technology innovations to be incorporated into it, to the extent possible, in order to remain commercially viable. The use of dynamic game balancing is also encouraged to provide an appropriate level of challenge to the patient. Following the completion of Phase II, it is expected that the products under development will be commercialized and disseminated.

Examples of research and development activities that would be appropriate topics for proposed Phase I/Phase II projects, include, but are not limited to, the following:

- Rapidly develop novel, engaging computer-based cognitive training programs that are based on efficacious neurotherapeutic approaches and which use cognitive training to target a specific neural system/functional domain.
- Augment existing computerized cognitive interventions to be personalized, engaging, adaptive, sufficiently challenging, and optimal for maximizing real world functional improvements.
- Test the feasibility, efficacy and potential adverse effects of these programs utilizing measures of functional outcomes in an identified clinical population, particularly those with neuropsychiatric disorders, ASD, and/or HAND, at a specified developmental stage, including measurement of the duration of treatment effects.

Small businesses new to the NIMH SBIR program are strongly encouraged to apply. While those types of small businesses will not be given special consideration during peer review, NIMH will consider them at the time of award. Small businesses that serve only to manage the project between entertainment software companies and clinical researchers will not be considered appropriate for this initiative and will be withdrawn as non-responsive. While managing the project between entertainment software programmers and clinical researchers is a factor, small businesses should have the scientific expertise and personnel to develop gaming technologies, a scientific understanding of cognition, and the ability to work cooperatively with clinical researchers on neuropsychiatric disorders.